

REMARKS

The claims have been amended in a manner that is believed to distinctly and clearly claim the subject matter that is regarded as applicants' invention. In particular, it is made clear that

Objection Under 35 USC 132(a)

The amendment filed 12/26/2007 is objected to because material that is not supported by the original disclosure is said to have been added. In particular, amended claim 3 recites that the tests to be performed are used to determine the period of storage time, which is represented in the bar code. In response, the Examiner's attention is called to page 11, paragraph [0036] where it is disclosed that:

Incoming specimens to be tested are identified by reading with a conventional bar code reader 49 bar coded indicia on sample tubes 14 to determine, among other items, a patient's identity, the tests to be performed, if a sample aliquot is desired to be retained and if so, for what period of time.

The context of this statement make is clear that "retained" means "retained in storage"; as such Applicants do not believe that new material has been introduced into claim 3 and respectfully request that the Examiner's objection under 35 USE 132(a) with withdrawn.

In view of the Examiner's requirement that the supposed new material be canceled in Response to the outstanding Office Action, claim 3 has been canceled and a new claim 11, based on the above disclosure, added in place thereof.

Claim Rejections –35 USC §112

Claims 1-10 are rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants view as their invention. Concerning the period of storage time, claim 1 has been amended to specify that the second aliquot portion contained in the aliquot storage vessel is stored within the storage compartment for a period of time that is identified in the bar code indicia. Support for this amendment may be found in paragraph [0041].

Concerning claim 3, in particular replacement claim 11, it is made clear that the bar code indicia identifies the tests to be performed upon a patient's specimen, whether or not the second aliquot portion is to be retained in storage, and the period of storage time the second aliquot portion is to be retained in storage. Support for this version of original claim 3 may be found in paragraphs [0036] and [0041].

Concerning claim 8, the information or data encoded in the bar code indicia identify the tests to be performed on a specimen (providing bar code indicia on the original sample container to indicate the tests to be completed on the patient's sample); the particular tests to be conducted identify how long the second aliquot of specimen is to be stored (using the identity of said tests to determine a storage period of time for said second aliquot portion). This is believed to be clear, in particular when taken with the example provided in paragraph [0043] as follows:

For example, if a Standard Metabolic Panel (CHEM 8) including Na, K, Cl, CO₂, GLUC, BUN, CREA, and CA is to be performed, the second sample aliquot may be automatically retained in an aliquot storage vessel 43 for a two week period of time.

Claims 9 and 10 have been amended to specify that the "indicia on the sample container" are the bar code indicia on the original sample container.

In view of the amendments and the discussion provided above, it is respectfully requested that the rejection of claims 1-10 under 35 USC §112, second paragraph, be withdrawn.

Claim Rejections –35 USC §102

Claims 1-3, 5 and 7-9 are rejected under 35 USC §102(a) as being anticipated by Young (US 3,565,582). The Examiner cites Young for teaching "methods and means for handling blood test specimens" wherein:

"some of the serum is transferred from the initial or first vessel to the other or second vessel. A sample of the specimen is withdrawn and is subjected to the test sequence which includes the testing and presentation of the test result. These steps, withdrawal of the sample, testing and presentation of test results are accomplished according to a predefined time schedule. An added step in the process, and one which may be accomplished at any point in the process this far described, is to apply to the container indicia or data which will identify the specimen and the test to which it is to be subjected" (col. 3, lines 60-72). "Upon withdrawal of a test sample a specimen upon which other tests are to be run is placed in storage and is then submitted to another timed sequence of steps including sample withdrawal, testing and presentation of test results. The storage step may be included in the time sequence of the steps. The step of reading the data in the container and correlating that data with test results will also be included in the timed sequence of steps. " (col. 4, lines 10-16).

What Young discloses in this section is no more than storing an original specimen on board an analyzer for possible subsequent processing as well as the use of indicia on the original sample container to identify tests to be conducted on the sample.

The Examiner further cites Young for disclosing:

"a double vessel container for blood and its serum, which is capable of bearing data identifying the blood and the test prescribed together with apparatus for reading that data and for conducting tests according to a predetermined relative time schedule" (col. 3, lines 48-53).

Here again, Young discloses no more than the use of indicia to identify tests to be conducted on a specimen (it is the testing apparatus that conducts tests according to a predetermined relative time schedule).

The Examiner also cites Young for disclosing:

"It is implicit in the preceding discussion that the several steps in the method may be separated by storage steps in which specimens are stored in the double vessel container. Any storage prior to application of identification data to the container must be controlled to prevent loss of identity. In addition, in the interval between removal of the sample and correlation of identification data and test result there must be a control to enable proper correlation which involves accomplishment of any storage steps on a timed basis for integral multiples of the unit time period employed in the process" (col. 8, lines 10-20) (which depends on the test to be performed, see col. 7).

"A cover 44 is provided for the container to insure cleanliness prior to use and to insure that the blood and serum are not contaminated with dirt and other foreign matter once they are placed in the container" (col. 6, lines 19-22).

Here Young only discloses that specimens are stored on the apparatus in a single container **10** having concentric vessel portions **12** and **18**, whole blood retained in inner vessel portion **12** and serum in outer vessel portion **18** (Col 5, lines 30-32).

The Examiner then states a belief "that the disclosure in terms, which were conventional for the state of the prior art in the time of Young's invention, covers the subject matter of the indicated claims."

Applicants note that the disclosures cited above teach only that an original specimen container be stored on board an analyzer for possible later testing. Young does not teach:

- extracting first and second aliquot portions of specimen from the original sample container and retaining the second aliquot portion in a storage vessel;
- performing tests on the first aliquot portion;
- storing the second aliquot portion within a storage compartment within an analyzer for a predetermined period of storage time

Since these limiting process steps are not disclosed by Young, an anticipation rejection under 35 USC §102(a) that requires disclosure of each and every feature of the claimed invention cannot be sustained. Applicants thus respectfully request that the rejection of claims 1-10 under 35 USC §102(a) be withdrawn.

Claim Rejections –35 USC §103

Claims 4, 6 and 10 are said to be rejected under 35 USC 102(b) as being anticipated by Young; however since this rejection is included under the §103 heading, the rejection will be treated as being an obviousness-type rejection. With regard to the rejection of these three claims under 35 USC 103, since claim 1 patentably distinguishes over Young and is allowable, claims 4, 6 and 10 are at least allowable therewith because they depend from an allowable claim. Consequently, the Examiner is requested to withdraw the rejection of claims 4, 6 and 10 under 35 USC 103.

Claims 1-4, 6 and 9-10 are rejected under 35 USC 103(a) as being unpatentable over Mazza (US 5,350,564) in view of Thorne et al (US 4,678,752, IDS). The Examiner cites Mazza for disclosing:

- 1) A conveyor system for feeding individual sample tubes . . . either from groups or batches . . . identifying the individual sample tubes and conveying and/or temporarily storing the individual sample tubes as required . . . while test results are obtained, and returning the tubes to groups in response to an indication that analysis of a particular sample is complete and verified as reliable.

2) This storage and dwell time feature makes possible the recall to an analyzer module of any particular sample in the event the results of a test are not verified as reliable. This latter feature is of high importance with stat samples. If the test results for any stat sample are not reliable, the sample will be recalled to the analyzer and retested. Only when the test results of each sample are verified will the sample be delivered to the off-loading area.

Mazza does no more than teach temporarily storing a sample until such time as valid test results are reported at which point in time, the sample are off-loaded from the analyzer. In contrast, Applicants' store a sample aliquot after the requisite tests are completed for a period of time that is identified by indicia on the original sample container. Claim 1 specifies:

- providing bar code indicia on the original sample container to indicate a predetermined period of storage time; and,
- storing an aliquot vessel containing a second aliquot portion within the analyzer for said predetermined period of storage time

As examples, attention is turned to paragraph [0041], wherein:

a second sample aliquot is taken by sample liquid probe 28 from every patient specimen placed in a sample cup 14 and is retained in an aliquot storage vessel 43 within environmentally controlled storage compartment 50 for a first predetermined period of time, for example two weeks, after tests on the corresponding first sample aliquot is taken by sample liquid probe 28 are completed.

And to paragraph [0044], wherein:

if the original patient specimen is to be tested for indications of abnormal levels of drugs of abuse or prostrate specific antigen, . . . the period of time that the second sample aliquot is retained in storage compartment 50 may be as short as one or two days, since no additional or repeated testing is expected. In contradistinction, . . . the period of time that the second sample aliquot is retained in storage compartment 50 may be as long as one or two weeks . .

Since Mazza only teaches storing a sample until such time as valid test results are reported, a time that may be as short as one hour, Mazza cannot make obvious Applicant's invention wherein a sample is stored for a period of

time (for example one or two days or one to two weeks) that is identified by indicia on the original sample container after the requisite tests are completed. The Examiner recognizes this on page 6, first new paragraph of the Action dated March 7, 2008 and repeats this limited teaching of Mazza on page 8, line 8, the sentence beginning, "In fact . . . repeated."

The Examiner thus turns to Thorne's disclosure of providing an expiration date for reagents in a bar code and suggests that it would have been obvious to modify Mazza's method "to discard the samples which were retained in the storage compartment for the period of time exceeding the expiration date (the time period) and to alert the user about the expiration of the time period."

Applicants recognize that the Supreme Court's opinion in the recent case *KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350 550 U. S. ____ (Apr. 30, 2007) concedes that "invention in most, if not all instances, rely upon building blocks long since uncovered, and claimed discoveries almost of necessity, will be combinations of what, in some sense, is already known" (*KSR*, slip op at 15). For this reason, the *KSR* rulings maintain that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art . . . and that it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." (*KSR*, slip op. at 14 bridging to 15, underlining added for emphasis)

In rejecting claims 1-4, 6 and 9-10 of the present application under 35 USC 103(a) as being unpatentable over Mazza in view of Thorne, the Examiner has suggested that the reason an artisan would combine the teachings of Mazza and Thorne is to avoid re-testing a sample that may be "degrading in time". Such a reason does not apply to the instant invention wherein samples are stored in "temperatures between minus 4 degrees Centigrade and plus 20 degrees Centigrade and relative humidity between about 5% and 75%", like maintained in storage compartment 50 (see paragraph [0037]) and under these condition, it is well know that samples do not degrade over periods of time like one to two weeks.

KSR further requires that "a court must ask if the improvement is more than the predictable use of prior-art elements according to their established functions." (*KSR*, slip op. at 4, underlining added for emphasis). In making the present rejection, the Examiner has added bar code information relating to the expiration date of a solution (a reagent, or in the instant invention, a patient's specimen) to a stored solution so as to enable an operator to "discard samples which were retained in the storage compartment for a period of time exceeding the expiration time or date." There is no reason to add information relative to the "expiration date of a sample" to an original sample container to indicate a predetermined period of storage time after tests on said first sample aliquot are completed, reported, or analyzed by a physician to allow for re-testing of the patient's specimen (Claim 1), or wherein bar code indicia are provided on the original sample container to indicate the tests to be completed on the patient's sample and using the identity of those tests to determine a storage period of time for a second aliquot portion (Claim 8).

For the above reasons, Applicants respectfully submit that the rejection of claims 1-4, 6 and 9-10 as being unpatentable under 35 USC 103(a) over Mazza and Thorne is believed to be overcome and is requested to be withdrawn.

Claim 5 is rejected under 35 USC 103(a) as being unpatentable over Mazza in view of Thorne et al and further in view of art, for example Boosalis et al (US 4,362,698, IDS). In response, since claim 1 patentably distinguishes over Young and is allowable, claim 5 is at least allowable therewith because it depends from an allowable claim. Consequently, the Examiner is requested to withdraw the rejection of claim 5 under 35 USC 103. For these reasons, the Examiner's rejection of claim 5 as being unpatentable is believed to be overcome and is requested to be withdrawn.

Conclusion

Applicants believe that this application contains patentable subject matter and that the foregoing amendments provide a basis for favorable consideration and allowance of all claims; such allowance is respectfully requested. If any matter needs to be resolved before allowance, the Examiner is encouraged to call Applicants' representative at the number provided below.

Respectfully submitted,



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